What recommendations can be made to patients to prevent transmission of hepatitis C?

The large reservoir of individuals infected with HCV provides a source of transmission to others at risk. Direct percutaneous exposure is the most efficient method for transmitting HCV, and injection drug use accounts for more than two-thirds of all new infections in the United States. Methadone treatment programs, needle and syringe exchange programs, and comprehensive risk-modifying educational programs have been shown to be effective in preventing HIV transmission and are likely to be useful for decreasing HCV transmission. Ensuring access to sterile syringes through physician prescription and pharmacy sales of syringes to IDUs can also be helpful. IDUs should be educated about the importance of hand washing before and after giving injections, not using the others' injection equipment, and avoiding any contact with blood from other persons. HCV prevention education should be a high priority in correctional settings. The majority of cases not attributed to injection drug use can be attributed to sexual contact and occupational exposures to blood, although the actual risk of transmission through these routes is low. Data regarding transmissibility by sexual contact have been confounded in part by other exposures, including injection drug use, that can increase the risk of transmission of HCV. HCV genotypes appear to have no impact on the risk of transmission.

HCV is rarely transmitted by transfusion of blood products or transplantation of organs or tissues in the United States and other countries where screening tests exclude infectious donors.

In the United States, the estimated seroprevalence of HCV is 2 to 3 percent among partners of HCV-infected persons who are in long-term monogamous relationships and is 4 to 6 percent among persons with multiple sex partners, sex workers, and men who have sex with men (those at risk for sexually transmitted diseases). One study found

the risk of HCV infection to be threefold higher for female than male sexual partners. Thus, sexual partners of male and female patients with hepatitis C should be tested for this infection. For heterosexual, discordant monogamous couples, the risk of transmission is estimated to be only 0 to 0.6 percent annually. Because of the low risk of HCV transmission, monogamous couples do not need to use barrier protection (condoms) although they should be advised that condoms may reduce the risk of transmission. However, HCV-infected individuals with multiple sexual partners or in short-term relationships should be advised to use condoms to prevent transmission of HCV and other sexually transmitted diseases. Sharing common household items that may be contaminated with blood, such as razors and toothbrushes, is another potential source of transmission of HCV that should be avoided. There is no evidence that kissing, hugging, sneezing, coughing, food, water, sharing eating utensils or drinking glasses, casual contact, or other contact without exposure to blood is associated with HCV transmission.

Healthcare workers have a similar or slightly lower prevalence of HCV infection than the general population, although they may have acquired their infection from occupational sources. Transmission from healthcare workers to patients has also been documented, but is rare and confounded by other risk factors. HCV-infected healthcare workers should use standard (universal) precautions to prevent transmission and should not be restricted in their employment.

The risk of HCV infection from a needlestick injury is estimated to be 2 percent. At this time, immune globulin or antiviral prophylaxis is not recommended following needlestick exposure. It is recommended that the source and exposed individual should be tested for antibody to HCV. If the source individual is HCV EIA positive, an immunoblot or HCV RNA assay should be done in the exposed individual. Since HCV RNA is first detected in the blood 2 weeks after transmission, the exposed individual should be tested for HCV antibody, HCV RNA, and ALT at exposure and again between 2 and 8 weeks after injury. If seroconversion occurs,

such persons should be referred to a specialist knowledgeable in this area for consideration of treatment.

Body piercing and tattooing are other potential sources of transmission if contaminated equipment or supplies are used. However, transmission through these activities is rare and confounded by other risk factors.

The risk of perinatal transmission is approximately 2 percent for infants of anti-HCV seropositive women. When a pregnant woman is HCV RNA positive at delivery, this risk increases to 4 to 7 percent. Higher HCV RNA levels appear to be associated with a greater risk. HCV transmission increases up to 20 percent in women co-infected with HCV and HIV. There are no prospective studies evaluating the use of elective cesarean section for the prevention of mother-to-infant transmission of HCV. However, avoiding fetal scalp monitoring and prolonged labor after rupture of membranes may reduce the risk of transmission to the infant. There are currently no data to determine whether antiviral therapy reduces perinatal transmission. Ribavirin and interferons are contraindicated during pregnancy. Breast-feeding does not appear to transmit HCV. Infants born to HCV-positive mothers should be tested for HCV infection by HCV RNA tests on two occasions between the ages of 2 and 6 months and/or have tests for anti-HCV after 15 months of age. Positive anti-HCV in infants prior to 15 months of age may be due to transplacental transfer of maternal anti-HCV antibody.

Children and personnel should not be excluded from day care centers, schools, or sports on the basis of HCV infection. Standard (universal) precautions should be used in any situation where exposure to blood occurs.

What are the most important areas for future research?

- The development of reliable, reproducible, and efficient culture systems for propagating the hepatitis C virus is considered to be of the highest priority. This goal is deemed essential not only for vaccine development but also for progress in fundamental aspects of HCV biology, hepatic tropism, and viral replication. Furthermore, this development will assist in new drug discovery, as well as enhance understanding of the mechanisms of drug resistance. Studies on the mechanisms of development of resistance to current and future antiviral therapies are particularly important.
- The role of genetic factors in the pathogenesis of HCV, including immune responses to infection, reasons for spontaneous resolution and variations in natural history, and responses to therapy, need further examination.
- Priority should be given to developing less-toxic therapies and molecular-based agents that specifically inhibit viral replication and/or translation of viral RNA.
- Hepatic fibrosis is the principal complication of chronic HCV infection leading to the development of cirrhosis and decompensated liver disease. Directed investigation examining the development and progression of fibrosis is, therefore, essential for effective management of these patients. Studies also are needed to examine fundamental mechanisms of fibrosis in response to HCV and to define rates of progression of fibrosis in patients with prolonged duration of HCV infection. Similarly, studies are needed to determine the natural history of fibrosis in populations including children, HIV co-infected patients, older adults, African Americans, Hispanics, HCV-infected patients with normal ALT levels, and IDUs. Evaluation of progressive fibrosis will best be accomplished with noninvasive tests capable of discriminating intermediate stages of fibrosis. Research into the development of noninvasive dynamic measures of hepatic fibrosis is strongly encouraged.

- Given the large number of persons with chronic HCV, the large number of untreated patients, and a compelling number of important areas for future research, we recommend that the NIH establish a Hepatitis Clinical Research Network. The goal of this network should be the conduct of research related to the natural history, prevention, and treatment of hepatitis C.
- Randomized controlled trials (RCTs) need to be carried out in special populations of patients not represented in current trials to determine the applicability of currently accepted treatment to these subgroups and the optimal doses and duration of therapy. These populations include children, patients with acute hepatitis, and patients in drug treatment programs. Research is also needed to define the best approaches to treating HCV in active drinkers, prisoners, those co-infected with HIV, patients with concurrent renal disease, and patients with major psychiatric illness. Therapies need to be developed for difficult treatment groups, including patients whose HCV infection does not respond to or who relapse after current therapy, patients with compensated and decompensated cirrhosis, transplant patients, and patients with adherence problems. Trials are also needed to establish optimal doses and duration of therapy for all populations of patients with chronic hepatitis C.
- Little information exists to describe the natural history of HCV viremia lasting 20 years or more. Studies are needed to examine the pattern of HCV disease progression in persons infected for at least two decades, including those infected as infants and as children.
- More investigation is needed into the prevalence and clinical significance of extra-hepatic manifestations of HCV.
- There is a need to assess the effectiveness of infection-control strategies, including practices in hemodialysis units and safe injection practices. Better understanding of factors that might predict transmission (e.g., phase

of infection), the risk of specific sexual practices, and the effectiveness of risk reduction counseling is needed. The effect of elective cesarean section on mother-to-infant transmission should be assessed.

- Given the significant side effects of accepted therapies, resources should be directed toward understanding side effect management and increasing patient adherence to therapy.
- Trials are needed in combination therapy nonresponders and those who cannot tolerate conventional therapies, comparing combinations of antifibrotic and anti-inflammatory agents, as well as immunomodulatory drugs and drugs that are directed specifically at HCV replication. Studies are also needed to assess the efficacy of alternative and nontraditional medicines.
- Because studies of acute hepatitis C are small in number, greater numbers of patients need to be included in clinical trials. Evidence-based data are needed to determine whom to treat and when to start therapy. Delays in treatment for 2 to 3 months seem reasonable to identify cases that spontaneously resolve. Weekly monotherapy with pegylated interferon with or without ribavirin for 12 to 24 weeks should be studied.
- Provision of educational programs about HCV for grades K–12 and college-age students is necessary, as is enhanced information related to risk factors for HCV for dissemination to the general public and the medical profession. Healthcare professional and healthcare advocacy organizations should be particularly active in this area.
- Although it is likely that HCV is highly prevalent in patient populations without health insurance or with publicly funded healthcare payers, no data to support this are available. The prevalence of HCV infection and the feasibility of management and treatment in these populations should be studied.
- There is a need to assess the effectiveness of supportive therapy to ameliorate the side effects of antiviral therapy.

- There is a need to more clearly establish the role of liver biopsy in the therapeutic management of patients with chronic hepatitis C. Biopsy techniques and their side effects need to be more clearly described during trials. The relationship of pretreatment histology to treatment outcomes needs better definition. The value of liver biopsy in patients with normal liver enzymes also needs evaluation, as does the need and timing for followup biopsies in patients with stage 0–1 fibrosis when treatment is deferred. The relationship of pretreatment histologic characteristics (including steatosis, iron deposition, and the pattern of fibrosis) to clinical outcomes (including progressive fibrosis and response to medical therapy) must be better defined. In addition, the requirement for direct assessment of hepatic histology by liver biopsy in the setting of non-genotype 1 infection should be critically evaluated. In the absence of sensitive non-invasive markers of fibrosis, liver biopsy remains essential for direct assessment of the degree of hepatic fibrosis. However, the precise interval for monitoring the progression of fibrosis in HCV-infected patients, in particular those populations most at risk for rapid progression, needs to be evaluated.
- International standardization of viral RNA titers is needed, along with a critical assessment of the utility of measuring viral kinetics as valid prognostic indicators of SVR and other clinically meaningful responses to therapy.
- RCTs are needed to assess screening tests in patients at greatest risk of HCC.
- Studies are needed to assess whether there are safe levels of alcohol consumption in patients with HCV and the effect of higher levels of alcohol use on disease progression.
- Investigations are needed into the role of fatty liver, obesity, diabetes, and hepatic iron stores in the natural history of hepatitis C and responses to therapy.
- Studies are needed in HIV co-infected patients to determine treatment outcomes and duration, maintenance therapy, treatment safety, and pathogenesis.

Conclusions

The incidence of newly acquired hepatitis C infection has diminished in the United States. This decline is largely due to a decrease in cases among IDUs for reasons that are unclear and, to a lesser extent, to testing of blood donors for HCV. The virus is transmitted by blood and such transmission now occurs primarily through injection drug use, sex with an infected partner or multiple partners, and occupational exposure. The majority of infections become chronic, and therefore the prevalence of HCV infections is high, with about 3 million Americans now estimated to be chronically infected. HCV is a leading cause of cirrhosis, a common cause of HCC and the leading cause of liver transplantation in the United States. The disease spectrum associated with HCV infection varies greatly. Various studies have suggested that 3 to 20 percent of chronically infected patients will develop cirrhosis over a 20-year period, and these patients are at risk for HCC. Persons who are older at the time of infection, patients with continuous exposure to alcohol, and those co-infected with HIV or HBV demonstrate accelerated progression to more advanced liver disease. Conversely, individuals infected at a younger age have little or no disease progression over several decades.

The diagnosis of chronic hepatitis C infection is often suggested by abnormalities in ALT levels and is established by EIA followed by confirmatory determination of HCV RNA. Several sensitive and specific assays are now partly automated for the purposes of detecting HCV RNA and quantifying the viral level. Although there is little correlation between viral level and disease manifestations, these assays have proven useful in identifying those patients who are more likely to benefit from treatment and, particularly, in demonstrating successful response to treatment as defined by an SVR. Liver biopsy is useful in defining baseline abnormalities of liver disease and in enabling patients and healthcare providers to reach a decision regarding antiviral therapy. Noninvasive tests do not currently provide the information that can be obtained through liver biopsy. Information on the genotype of the virus is important to guide treatment

decisions. Genotype 1, most commonly found in the United States, is less amenable to treatment than genotypes 2 or 3. Therefore, clinical trials of antiviral therapies require genotyping information for appropriate stratification of subjects.

Recent therapeutic trials in defined, selected populations have clearly shown that combinations of interferons and ribavirin are more effective than monotherapy. Moreover, trials using pegylated interferons have yielded improved SVR rates with similar toxicity profiles. However, results continue to show that the SVR rate is less common in patients with genotype 1 infections, higher HCV RNA levels, or more advanced stages of fibrosis. Genotype 1 infections require therapy for 48 weeks, whereas shorter treatment is feasible in genotype 2 and 3 infections. In genotype 1, the lack of an early virologic response (< 2 log decrease in HCV RNA) is associated with failure to achieve an SVR. The SVR is lower in patients with advanced liver disease than in patients without cirrhosis.

Ongoing trials are exploring the usefulness of combination therapy in various populations. Preliminary experience in IDUs, individuals co-infected with HIV, children, and other special groups suggests similar responses are achievable in these populations. Patients with acute hepatitis C may be treated, but specific recommendations for antiviral treatment must await further evaluation of the rate of spontaneous clearance of the virus and determination of the optimal time to initiate treatment.

Preventive measures beyond blood-banking practices include prompt identification of infected individuals, awareness of the potential for perinatal transmission, implementation of safe-injection practices, linkage of drug users to drug treatment programs, and implementation of community-based education and support programs to modify risk behavior. Some of these measures have been successfully implemented in the control of HIV infections, and it stands to reason that they would be valuable for reducing HCV transmission.

Future advances in the diagnosis and management of hepatitis C require continued vigilance concerning the transmission of this infection, extending treatment to populations not previously evaluated in treatment trials, and the introduction of more effective therapies.

Recommendations

- Educate the American public on the transmission of HCV in order to better identify affected individuals and to institute preventive measures.
- Develop reliable, reproducible, and efficient culture systems for propagating HCV and expand basic research in the pathogenic mechanisms underlying hepatic fibrosis.
- Promote the standardization and wide availability of diagnostic tests for HCV infection and its complications, leading to early diagnosis and the implementation of appropriate treatment practices.
- Promote the establishment of screening tests for all groups at high risk of HCV infection, including IDUs and incarcerated individuals.
- Expand the delineation of disease manifestations, noninvasive tests, and the role of the liver biopsy, so that the application of current treatment practices may be refined.
- Establish a Hepatitis Clinical Research Network for the purpose of conducting research related to the natural history, prevention, and treatment of hepatitis C.
- Organize RCTs to extend treatment to special populations not represented in current clinical trials and to determine the applicability of accepted antiviral drug combinations to populations such as children and adolescents, and

patients with acute hepatitis. Effective approaches are needed for drug users receiving drug treatment, alcohol abusers, prisoners, patients with stabilized depression, those with co-infection with HIV, patients with decompensated cirrhosis, and HCV infections in transplant recipients. Such efforts should lead to decreased morbidity and mortality from the disease, as well as a decrease in the reservoir of disease.

- Institute measures to reduce transmission of HCV among IDUs, including providing access to sterile syringes through needle exchange, physician prescription, and pharmacy sales; and expanding the Nation's capacity to provide treatment for substance abuse. Physicians and pharmacists should be educated to recognize that providing IDUs with access to sterile syringes and education in safe injection practices may be lifesaving.
- Evaluate strategies to interrupt mother-to-infant transmission of HCV.
- Compare new therapies to current treatments in nonresponders, to include not just antiviral agents but also combinations of antifibrotic drugs, immunomodulatory agents, and alternative therapies.
- Encourage a comprehensive approach to promote the collaboration among health professionals concerned with management of addiction, primary care physicians, and specialists involved in various aspects of HCV—to deal with the complex societal, medical, and psychiatric issues of IDUs afflicted by the disease.
- Seek appropriate support from governmental agencies and the private sector to address urgent research questions concerning the epidemiology and treatment of this disease.

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